

## **ANACIN AF- acetaminophen, aspirin and caffeine tablet, coated**

### **Insight Pharmaceuticals**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**ANACIN®**

**ADVANCED**

**HEADACHE FORMULA**

### ***Drug Facts***

#### **Active ingredients (in each tablet)**

Acetaminophen 250 mg

Aspirin 250 mg

Caffeine 65 mg

#### **Purposes**

Pain reliever

Pain reliever

Pain reliever aid

#### **Uses**

temporarily relieves minor aches and pains due to:

- headache
- a cold
- toothache
- muscular aches
- arthritis
- menstrual cramps

#### **Warnings**

##### **Reye's syndrome**

Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

##### **Allergy alert**

Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

## **Alcohol warning**

If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen and aspirin or other pain relievers/fever reducers. Acetaminophen and aspirin may cause liver damage and stomach bleeding.

## **Do not use**

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- with any other products containing acetaminophen. Taking more than directed may cause liver damage.

## **Ask a doctor before use if you have**

- asthma
- ulcers
- bleeding problems
- stomach problems such as heartburn, upset stomach, or stomach pain that do not go away or return

## **Ask a doctor or pharmacist before use if you are** taking a prescription drug for:

- anticoagulation (thinning of the blood)
- diabetes
- gout
- arthritis

## **Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- new symptoms occur
- symptoms do not get better or worsen
- ringing in the ears or loss of hearing occurs
- painful area is red or swollen
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days

## **Caffeine warning**

The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid heart beat.

**If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.**

## **Overdose warning**

Taking more than the recommended dose can cause serious health problems. In the case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

## **Directions**

- do not use more than directed (see overdose warning)
- drink a full glass of water with each dose

- adults and children 12 years of age and over: take 2 tablets every 6 hours; not more than 8 tablets in 24 hours, or as directed by a doctor
- children under 12 years: ask a doctor

**Other information**

- read all product information before using.
- store at 20°–25°C (68°–77°F). Protect from moisture.

**Inactive ingredients**

Colloidal Silicon Dioxide, Crospovidone, Lecithin, Microcrystalline Cellulose, Polyvinyl Alcohol, Povidone, Pregelatinized Starch, Sodium Starch Glycolate, Starch, Stearic Acid, Talc, Titanium Dioxide

Distributed by: **INSIGHT Pharmaceuticals Corp.**, Langhorne, PA 19047-1749

**Questions?**

Call 1-800-344-7239 or visit us at **www.anacin.com**

70126A

**PRINCIPAL DISPLAY PANEL - 75 tablet bottle label**

**NEW**

**ANACIN®**

**ADVANCED**

**HEADACHE FORMULA**

**PAIN RELIEF**

**CONTAINS**

**ACETAMINOPHEN,**

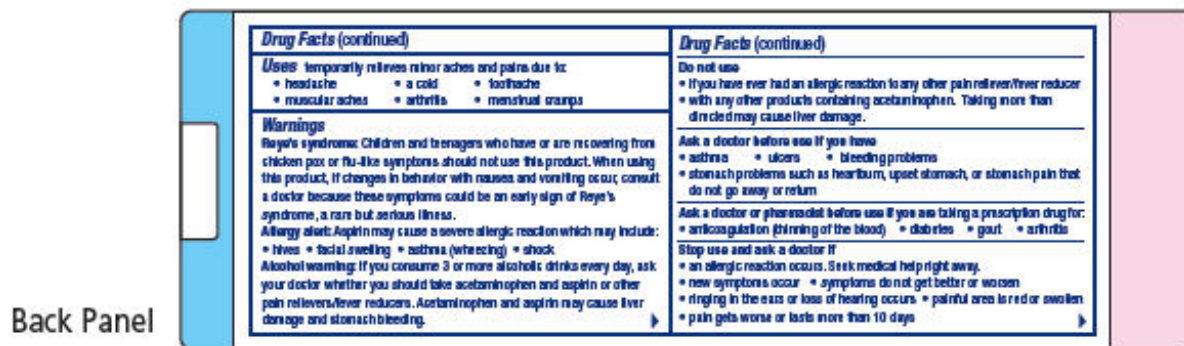
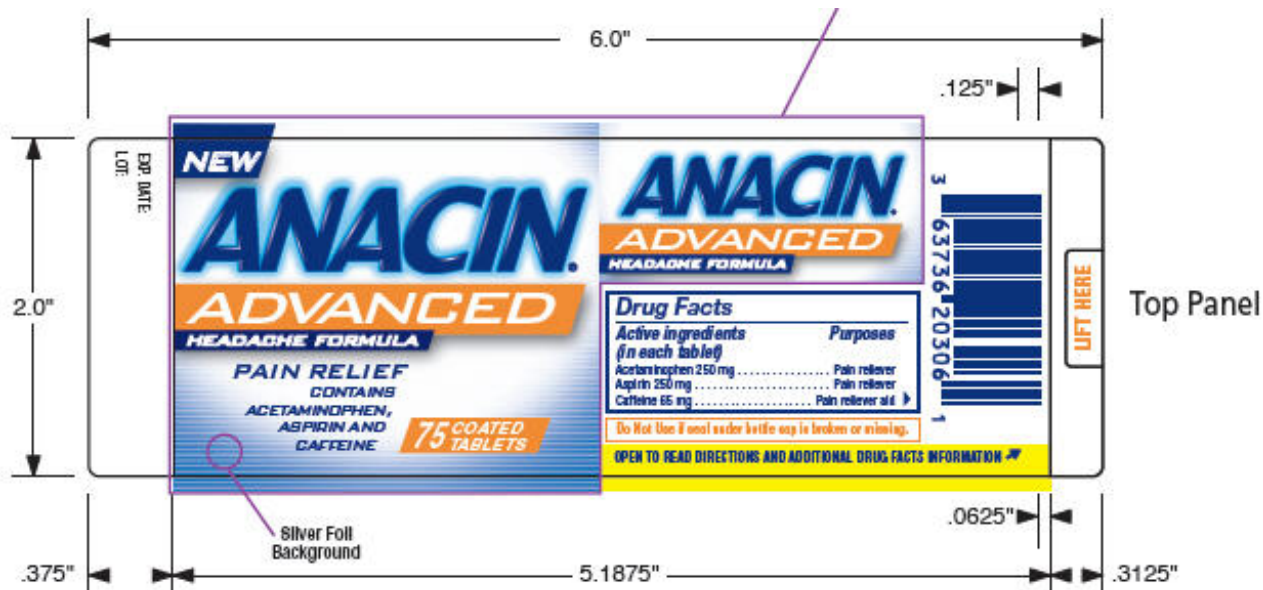
**ASPIRIN AND**

**CAFFEINE**

**75**

**COATED**

**TABLETS**



## PRINCIPAL DISPLAY PANEL - 75 tablet carton

**NEW**  
**ANACIN®**  
**ADVANCED**  
**HEADACHE FORMULA**  
**PAIN RELIEF**  
**CONTAINS ACETAMINOPHEN,**  
**ASPIRIN AND CAFFEINE**

**75**  
**COATED**  
**TABLETS**



## ANACIN AF

acetaminophen, aspirin and caffeine tablet, coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-203
Route of Administration	ORAL	DEA Schedule	

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)		Acetaminophen	250 mg	
Aspirin (UNII: R16CO5Y76E) (Aspirin - UNII:R16CO5Y76E)		Aspirin	250 mg	
Caffeine (UNII: 3G6A5W338E) (Caffeine - UNII:3G6A5W338E)		Caffeine	65 mg	
Inactive Ingredients				
Ingredient Name			Strength	
Silicon Dioxide (UNII: ETJ7Z6XBU4)				
Crospovidone (UNII: 68401960MK)				
Cellulose, Microcrystalline (UNII: OP1R32D61U)				
Polyvinyl Alcohol (UNII: 532B59J990)				
Povidone (UNII: FZ989GH94E)				
Starch, Corn (UNII: O8232NY3SJ)				
Sodium Starch Glycolate Type A Potato (UNII: 5856J3G2A2)				
Stearic Acid (UNII: 4ELV7Z65AP)				
Talc (UNII: 7SEV7J4R1U)				
Titanium Dioxide (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	WHITE	Score	no score	
Shape	CAPSULE	Size	11mm	
Flavor		Imprint Code	323	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-203-75	1 in 1 BOX		
1		75 in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part343		06/29/2009	

**Labeler** - Insight Pharmaceuticals (176792315)

Revised: 7/2009

Insight Pharmaceuticals